Remarks

Amendments to claim 2

Claim 2 is amended to correct a clerical error. The word "disease" was deleted accidentally in the previous amendment.

Rejection of Claims 2, 27, and 28 Under 35 U.S.C. § 112, first paragraph

Claims 2, 27, and 28 stand rejected as insufficiently described under 35 U.S.C. § 121 ¶1. The Patent Office contends that the specification does not support the claimed methods because "it does not disclose any agent found by the screening method, does not show any agent administered for any function, and provides no nexus between activity of PDE10A and any cardiovascular condition (or any other diseases as claimed)." Office Action at page 3, lines 1-5. Applicants respectfully traverse the rejection.

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing then the written description requirement is met. *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 155, 1563, 19 U.S.P.Q. 2d 1111, 1116 (Fed. Cir. 1991). In making a rejection for inadequate written description, the burden is on the Patent Office to present sufficient evidence why a person skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. *See In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). The Patent Office has not met that burden here.

All three pending claims recite methods of screening for therapeutic agents. The specification need not identify a specific agent nor describe administration of an agent to provide adequate written support for the claimed methods. In contrast to the Office Action's assertion, one of skill in the art would understand from the teachings of the specification that the claimed

methods can be used to identify useful therapeutic agents because the specification describes an adequate nexus between the recited diseases and PDE10A.

Claim 2 recites "cardiovascular disease." The specification supports a nexus between cardiovascular diseases and PDE10A:

> The human PDE10A is highly expressed in the following cardiovascular related tissues: fetal heart, heart, pericardium, heart atrium (right), heart atrium (left), heart ventricle (left), interventricular septum, fetal aorta, coronary artery smooth muscle primary cells, HUVEC cells. Expression in the above mentioned tissues demonstrates that the human PDE10A or mRNA can be utilized to diagnose [of] cardiovascular diseases. Additionally the activity of the human PDE10A can be modulated to treat cardiovascular diseases.

Specification at page 59, lines 1-7.

Claim 27 recites "gastroenterological diseases." The specification also supports a nexus between PDE10A and gastroenterological diseases. The specification teaches that PDE10A is differentially expressed between healthy and diseased tissues of the gastroenterological system (*e.g.*, between normal esophagus and esophageal tumor, normal stomach and stomach tumor, normal liver and cirrhotic liver, and normal liver and liver tumor). Specification at page 60, lines 20-30. The specification teaches that this differential expression "demonstrates that the human PDE10 or mRNA can be utilized to diagnose [of] gastroenterological disorders. Additionally the activity of the human PDE10A can be modulated to treat gastroenterological disorders." Specification at page 60, lines 28-30.

Claim 27 recites "cancer." The specification supports a nexus between cancer and PDE10A at page 68, lines 10-21. The specification teaches the differential expression of PDE10A between many sets of normal and tumor tissues: thyroid, esophagus, stomach, liver, cervix, ovary, and kidney. The specification teaches that this differential expression "demonstrates that the human PDE10A or mRNA can be utilized to diagnose [of] cancer.

Additionally the activity of the human PDE10A can be modulated to treat cancer." Specification at page 68, lines 18-20.

Claim 27 also recites "endocrinological diseases." Again, the specification teaches differential expression between normal and diseased tissues of the endocrine system, which supports a nexus between PDE10A and endocrinological disorders:

> The human PDE10A is highly expressed in the following tissues of the endocrinological system: thyroid, thyroid tumor and pancreas. The expression in the above mentioned tissues in particular the differential expression between diseased tissue thyroid tumor and healthy tissue thyroid, demonstrates that the human PDE10A or mRNA can be utilized to diagnose [of] endocrinological disorders. Additionally the activity of the human PDE10A can be modulated to treat endocrinological disorders.

Specification at page 65, lines 12-18.

Claim 27 also recites "urological diseases." The nexus between urological diseases and PDE10A is supported at page 69, lines 10-16 of the specification, which teaches high expression of PDE10A *inter alia* in prostate, bladder, ureter, fetal kidney, and kidney. The specification teaches that "the human PDE10A or mRNA can be utilized to diagnose [of] urological disorders. Additionally, the activity of the human PDE10A can be modulated to treat urological disorders." Specification at page 69, lines 15-16.

Claim 28 recites Alzheimer's disease. The specification supports a nexus between PDE10A and Alzheimer's disease because it teaches the differential expression of PDE10A in normal brain tissues versus Alzheimer's disease brain tissue. See the paragraph spanning pages 55 and 56.

The skilled artisan would recognize that elevated expression of PDE10A in diseased tissue versus normal tissue supports a nexus between PDE10A and the diseases recited in claims

2, 27, and 28. Indeed, as taught in the specification, the skilled artisan knew at this application's priority date that many phosphodiesterase isoforms exist and are known to have roles in disease: "Furthermore, the value as pharmaceutical targets has been proven for several PDEs. Selective inhibitors have been developed as therapeutic agents for diseases such as therapeutic agents for diseases such as cancer, heart failure, depression and sexual dysfunction." Specification at page 5, lines 18-20. The Patent Office has the burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in the specification a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). M.P.E.P. § 2163.04. In this case, the Patent Office offers no support for the proposition at all. In place of an explanation why the skilled artisan would not recognize applicant had possession of the invention, the Office Action merely concludes with the general allegation that "no specifics are found in the specification." Office Action at page 3. This is not sufficient to meet the Patent Office's burden.

The specification adequately describes the subject matter of claims 2, 27, and 28. Please withdraw the rejection.

Respectfully submitted,
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